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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,545	09/30/2003	Jason Fox	50623.00286 (ACS 3956)	7658

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EXAMINER

EDWARDS, LAURA ESTELLE

ART UNIT	PAPER NUMBER
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1734

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/676,545

Applicant(s)

FOX ET AL.

Examiner

Laura Edwards

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 17-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-16, drawn to an apparatus, classified in class 118, subclass 500.
- II. Claims 17-21, drawn to a method, classified in class 427, subclass 2.24.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the apparatus as claimed could be used as an arterial obstruction removal type endoscope whereby no coating is used with the apparatus.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with M. Lupkowski on 9/14/05 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-16. Affirmation of this election must be made by applicant in replying to this Office action. Claims 17-21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenbluth (US 4,762,128).

Rosenbluth establishes the conventional use of a balloon type catheter as a fixture to support or hold a stent during coating (see col. 10, lines 62-68), the fixture including a hollow tubular member (8) configured to be inserted into a longitudinal bore of a stent (18); a rod (2, 12) extending through the tubular member; and a pressurized fluid supply mechanism (see col. 5, lines 44 to col. 6, line 7) to cause the tubular member to expand and retract to support the stent.

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Claims 10-12, 14, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Lorentzen Cornelius et al (US 6,270,504).

Lorentzen C. et al provide an expandable/contractable balloon type catheter as a fixture to support or hold a stent, the balloon catheter being capable of supporting or holding a stent (20) during coating because an outer surface area of the stent is exposed for receipt of a fluid, the fixture including a hollow tubular member (14) configured to be inserted into a longitudinal bore of a stent (20); a rod (18) extending through the tubular member; and a mechanism (see col. 4, lines 4 to line 25) to cause the tubular member to expand and retract to support the stent (See Figs. 1 and 2).

With respect to claim 14, the fixture includes a mandrel base (16), a rod extending therefrom (18), and a support element (14) integrated with a rod.

Claims 1, 2, 4, 6, 8, and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Boulais (PAPUS 2004/0213893).

Boulais teaches a masking element (1) configured to be inserted through a bore of a stent, the masking element having an expanded configuration and a retracted configuration; and an expansion causing mechanism (col. 4, [0024]) capable of expanding the masking element from the retracted configuration to the expanded configuration to cause the masking element to make contact with and mask an inner surface of the stent during coating.

With respect to claim 4, see hollow rod or ports (7 or 8).

***Claim Rejections - 35 USC § 103***

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boulais (PAPUS 2004/0213893) in view of Pasqualucci et al (US 5,578,048).

The teachings of Boulais have been mentioned above but Boulais is silent concerning the balloon type member including a rod having a threaded portion supporting the masking element and a nut such that rotation of the nut on the threaded portion of the rod causes the masking element to expand and retract. However, it was known in the art, at the time the invention was made, to provide on a balloon type catheter, a rod within the balloon member, the rod having a threaded portion supporting the masking element and a nut such that rotation of the nut on the threaded portion of the rod causes the masking element to expand and retract as evidenced by Pasqualucci et al (see col. 3, lines 25-28). In light of the teachings of Pasqualucci et al, it would have been obvious to one of ordinary skill in the art to provide, as an alternative means for expanding and contracting the balloon masking member of Boulais, a rod having a threaded

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portion supporting the balloon masking member and a nut such that rotation of the nut on the threaded portion of the rod causes the masking element to expand and retract.

With respect to claim 5, Boulais recognize that the masking element can be rotated during coating of the stent (see col. 4, [0027], such that one of ordinary skill in the art would expect to couple a rotating mechanism to the apparatus as defined by the combination above in order to enable coating of all surfaces of the stent as a source of fluid whether from a stationary pump or gas supplying cylinder is provided to the balloon masking member.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenbluth (US 4,762,128) in view of Boulais (PAPUS 2004/0213893).

The teachings of Rosenbluth have been mentioned above but Rosenbluth is silent concerning the balloon type tubular masking member being designed or configured to expand to a degree such that the member extends partially through gaped regions of the stent. However, it was known in the art, at the time the invention was made, to provide an expandable hollow tubular member for holding a stent during coating and design or configure the tubular member so as to expand partially through gaped regions of the stent so as to avoid bridging of coating across stent lattice openings as evidenced by Boulais (see col. 4, [0029]). It would have been obvious to one of ordinary skill in the art to provide a tubular member designed or configured to expand partially through gaped regions of the stent as taught by Boulais in the Rosenbluth device in order to avoid bridging of coating across stent lattice openings.

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Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lorentzen Cornelius et al (US 6,270,504) in view of Boulais (PAPUS 2004/0213893).

The teachings of Lorentzen C. et al have been mentioned above but such teachings do not include a balloon type tubular masking member being designed or configured to expand to a degree such that the member extends partially through gaped regions of the stent. However, it was known in the art, at the time the invention was made, to provide an expandable hollow tubular member for holding a stent during coating and design or configure the tubular member so as to expand partially through gaped regions of the stent so as to avoid bridging of coating across stent lattice openings as evidenced by Boulais (see col. 4, [0029]). It would have been obvious to one of ordinary skill in the art to provide a tubular member designed or configured to expand partially through gaped regions of the stent as taught by Boulais in the Lorentzen C. et al device in order to avoid bridging of coating across stent lattice openings.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lorentzen Cornelius et al (US 6,270,504) in view of Wittenberger et al (US 6,575,933).

The teachings of Lorentzen C. et al have been mentioned above but such teachings do not include a lever to drive the rod in and out of the mandrel base. However, it was known in the art, at the time the invention was made, to provide a lever or switch to drive a coiled rod disposed within an expandable tubular member of a balloon type catheter to expand and contract the tubular member as taught by Wittenberger et al (see col. 6, lines 30-43). It would have been obvious to one of ordinary skill in the art to incorporate a lever type drive member as taught by Wittenberger et al in the tubular member of the Lorentzen C. et al device as an alternative



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mechanical means for expanding and contracting the expandable tubular member without the need of a source or supply of gas or fluid.

Claims 1, 2, and 4-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wittenberger et al (US 6,575,933) in view of Boulais (PAPUS 2004/0213893).

Wittenberger et al teach a balloon type catheter comprising a tubular support element capable of holding and supporting a stent, the support element being capable of expanding and contracting, the support element configured to be inserted through a bore of a stent; and an expansion causing mechanism (col. 6, lines 30-43[0024]). Wittenberger et al are silent concerning the tubular support element being expandable so as to define a mask for a stent mounted thereon. However, it was known in the art, at the time the invention was made, to provide an expandable hollow tubular member for holding a stent during coating and design or configure the tubular member so as to expand partially through gaped regions of the stent so as mask the stent for coating and to avoid bridging of the coating across stent lattice openings as evidenced by Boulais (see col. 4, [0029]). It would have been obvious to one of ordinary skill in the art to provide a tubular member designed or configured to expand partially through gaped regions of the stent as taught by Boulais in the Wittenberger et al balloon catheter device in order to enable multiple use of the balloon type catheter as a masking device, a delivery device, and/or a masking device for coating of the stent.

With respect to claim 4, Wittenberger et al recognize that cryogenic fluid can be supplied to the tubular member and Boulais recognizes that fluid can be supplied to the tubular masking element, such that it is within the purview of one skilled in the art to incorporate a fluid

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supplying rod in communication with the tubular member in the device as defined by the combination above.

With respect to claim 5, even though Wittenberger et al are silent concerning the balloon type catheter being coupled to rotating mechanism via a coupler in communication with a stationary source of supply fluid, Boulais recognizes that the masking element can be rotated during coating of the stent while in communication with a stationary source of supply fluid (see col. 4, [0027], such that one of ordinary skill in the art would expect to connect a rotating mechanism via a coupler to the device as defined by the combination above in order to enable coating of all surfaces of the stent as a source of fluid whether from a stationary pump or gas supplying cylinder is provided to the tubular member.

With respect to claim 7, Wittenberger et al recognize an expansion causing mechanism comprising including a helical coil member (220) engages with the expandable tubular element such that a [toggle] switch is used to drive the helical coil member to expand and contract within the tubular element (see col. 6, lines 30-43).

### ***Conclusion***

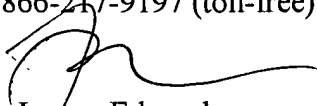
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following patent discloses the state of the art with respect to a non-tubular balloon type catheter having minimal points of contact with the interior of a stent: Hillstead (US 5,037,392).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura Edwards whose telephone number is (571) 272-1227. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Fiorilla can be reached on (571) 272-1187. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Laura Edwards  
Primary Examiner  
Art Unit 1734

Le  
September 30, 2005